REMARKS

Claims 1-15 are pending in the above-captioned application. By this Amendment, claims 1-4 are amended, claims 16-41 are added, and claims 5-15 have been canceled without prejudice or disclaimer. No new matter is added by this Amendment, and this Amendment is fully supported by the specification. It is respectfully submitted that claims 1-4 and 16-41 are in condition for allowance in view of the amendments and remarks presented herein.

SUMMARY OF ACTION

The Office Action objects to claim 13 for depending from the incorrect claim. The Office Action rejects claims 1, 2, 4 and 5 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2002-0142119 (Seward et al.). The Office Action also rejects claims 3 and 10-15 under 35 U.S.C. §103(a) as being obvious over U.S. Patent Application Publication No. 2002-0142119 as applied to claim 1. The Office Action also rejects claims 6-9 under 35 U.S.C. §103(a) as being obvious over U.S. Patent Application Publication No. 2002-0142119 as applied to claim 1 and further in view of U.S. Patent No. 6,388,043 (Langer et al.).

I. Objection of Claim 13

The Office Action objects to claim 13 for depending from the incorrect claim.

The Office Action states that "the Examiner believes that claims 13 should depend from claim 12, not claim 11" and request correction.

By this Amendment claim 13 has been canceled without prejudice or disclaimer. It is respectfully submitted, therefore, that this objection is moot.

II. Rejection of Claims 1, 2, 4 and 5 under 35 U.S.C. §102(e)

The Office Action rejects claims 1, 2, 4 and 5 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2002-0142119 (Seward et al.).

Claim 1 is independent. Claims 2 and 4 depend from independent claim 1. Claim 5 has been canceled without prejudice or disclaimer.

The Office Action states that U.S. Patent Application Publication No. 2002-0142119 "disclose[s] the invention as claimed including a stent made out of an SMP material (par. 77), the material having a

two-shape memory (par. 76), the material being made from a polymer network (par. 54), the SMP effect induced thermally (par 46-50), and the SMP material being biocompatible."

The Office Action asserts that paragraph [0077] of U.S. Patent Application Publication No. 2002-0142119 describes a stent made out of an SMP material. Paragraph [0077] of U.S. Patent Application Publication No. 2002-0142119 (reproduced below), however, describes a stent made of a combination of an SMP material and a metallic shape memory alloy ("SMA"):

> Reversible delivery, deployment, and repositioning of devices such as stents and embolic material can be achieved using an SMA/SMP actuator. The device can either be incorporated into the tip of a catheter, or form the stent itself. **When used as a stent, a coiled element or net-like tube of SMA material is embedded into an SMP sheath.** If a SMA spring is utilized, it is compressed during the SMP molding process, and expands when heated above the SMA transformation temperature, applying and outward pressure on the blood vessel. If improperly positioned, the device can be heated above the SMP transformation (but below the SMA transformation) temperature, at which point the SMP sheath will recompress the SMA spring, and the stent will shrink to its original diameter. When forming the tip of a catheter, the SMA/SMP actuator can be made to expand in diameter or length, and shrink in order to release, position, or grab therapeutic devices.

(Emphasis added). The first sentence of cited paragraph [0076] ("The final configurations for a **composite stent made from SMA and SMP** are shown in FIGS. 12A-12D and 13A-13B." (emphasis added)) and paragraphs [0078] and [0079] further emphasize this critical point:

> **The embodiments of FIGS. 12A-12D and 13A-13B utilize a stent created from SMA material by weaving a net-like tube that is embedded in a SMP sheath or tube.** The action of opening and closing of a stent is shown in FIGS. 12A-12D, while the action of releasing and recapturing a deliverable object is shown in FIGS. 13A-13B.
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> **FIGS. 12A-12D illustrates a SMA stent with a SMP wall coating for reversible stent deployment and positioning.** As shown, the actuator embodiment 70 comprises net-like SMA stent 71 with a SMP wall or coating 72, as shown in FIG. 12A, whereby the stent 71 is embedded within the SMP wall 72, having a central opening 73, as seen in FIG. 12B. Applying heat above SMA and SMP transformation temperatures causes the SMA stent 71 and SMP wall 72 to enlarge in diameter and shrink in length as shown in FIGS. 12C and 12D, and as indicated by arrow 74, whereby the stent 71 is opened, for use such as supporting a wall of a blood vessel. By then applying heat only above the SMP transformation temperature the stent 71 and SMP wall 72 shrink in diameter and stretch in length and thus return to the original configuration shown in FIGS. 12A-12B, as indicated by arrow 75, whereby the stent 71 can be repositioned or removed.
>
> (Emphasis added).

In reviewing U.S. Patent Application Publication No. 2002-0142119, Applicants were unable to find any examples of a stent made from anything other than a combination/composite of an SMA and an SMP. Although U.S. Patent Application Publication No. 2002-0142119 ostensibly suggests that the SMA and SMP materials can be used independently (*see, e.g.*, ¶ [0041]; "The present invention is directed to methods and means (devices) which enhance the use of catheters for minimally invasive techniques, and which involve the use of shape memory alloy (SMA) and shape memory polymer (SMP) materials which can be used singularly, in combination, or as a composite."), it appears that all of the figures and embodiments are directed to devices and methods employing a combination of an SMA and SMP. Indeed, paragraph [0043] states as much: "The composite and combined structures of the invention incorporate both SMA and SMP materials wherein, for example, the SMA material is embedded within the SMP material as a bistable composite, or the SMA material is wrapped around the SMP material, or the SMA material is patterned on the surface of the SMP so as to enable reversibility."

Thus, U.S. Patent Application Publication No. 2002-0142119 does not teach or suggest "A stent comprising (a) at least one of (i) a material consisting essentially of a non-metallic shape memory polymer (SMP) and/or (ii) a scaffold comprising a non-shape memory material that supports at least one material consisting essentially of at least one non-metallic SMP and (b) optionally at least one non-shape memory ingredient; wherein said SMP has up to two stimuli-triggered shapes in memory and wherein the stent contains no other shape memory materials other than the at least one non-metallic SMP" as recited by independent claim 1. Put another way, independent claim 1 is generally directed to stent that (1) includes no other shape materials (*e.g.*, SMAs) and (2) the stent structure itself is made primarily or entirely of a material consisting essentially of a non-metallic SMP and/or a non-shape memory scaffold supporting a material consisting essentially of a non-metallic SMP. In either case, the stent does not employ an SMA (or any other shape memory material) as taught and described in the cited portions of U.S. Patent Application Publication No. 2002-0142119.

Thus, the cited portions of U.S. Patent Application Publication No. 2002-0142119 cannot anticipate independent claim 1.

In view of the foregoing, withdrawal of the rejection of independent claim 1 under 35 U.S.C. §102(e) is respectfully requested.

Claims 2 and 4 depend from independent claim 1. As such, withdrawal of the rejections of dependent claims 2 and 4 under 35 U.S.C. §102(e) is also respectfully requested for at least the reasons described above in connection with independent claim 1 and for the additional features each recites.

III. Rejections Under 35 U.S.C. §103

1. Rejection of Claims 3 and 10-15 under 35 U.S.C. §103

The Office Action rejects claims 3 and 10-15 under 35 U.S.C. §103(a) as being obvious over U.S. Patent Application Publication No. 2002-0142119 as applied to claim 1.

Claim 3 depends from independent claim 1. Claims 10-15 have been canceled without prejudice or disclaimer. New claims 31-36 (which depend directly or indirectly from independent claim 1) and new claims 37-41 are generally directed to the subject matter of canceled claims 10-15.

The Office Action asserts that "[c]laims 3 and 10-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Seward et al. as applied to claim 1." Among other things, the Office Actions asserts that U.S. Patent Application Publication No. 2002-0142119 discloses (i) implanting and removing a stent and (ii) that it would have been obvious to have modified U.S. Patent Application Publication No. 2002-0142119 with either of an X-ray contrast substance and medically effective compound even though X-ray contrast substances and medically effective compounds are not taught in U.S. Patent Application Publication No. 2002-0142119.

Applicants reiterate the remarks set forth above regarding U.S. Patent Application Publication No. 2002-0142119 as applied to claim 1 (*i.e.*, that U.S. Patent Application Publication No. 2002-0142119 discloses devices made from a combination of an SMA and an SMP and the present claims are instead directed to a stent that (i) does not include any SMA or other shape memory materials other than the non-metallic SMP(s) and (ii) the stent itself is composed primarily or entirely of at least one material consisting essentially of at least one non-metallic SMP(s)).

Even assuming *arguendo* that U.S. Patent Application Publication No. 2002-0142119 discloses implanting and removing a stent and/or that it would have been obvious to modify U.S. Patent Application Publication No. 2002-0142119 with either of an X-ray contrast substances and medically effective compound, these assertions nonetheless fail to supply the deficiencies of U.S. Patent Application Publication No. 2002-0142119 as discussed above in conjunction with independent claim 1. Moreover, there is no teaching or suggestion, nor does the Office Action provide

a rationale, for modifying the teachings of U.S. Patent Application Publication No. 2002-0142119 to remedy those deficiencies in order to arrive at the compositions of the present claims.

Therefore, withdrawal of the rejection of dependent claim 3 under 35 U.S.C. § 103(a) is respectfully requested. Additionally, it is respectfully submitted that new claims 31-41 cannot be rendered obvious under 35 U.S.C. § 103(a) over U.S. Patent Application Publication No. 2002-0142119.

2. Rejection of Claims 6-9 under 35 U.S.C. §103

The Office Action rejects claims 6-9 under 35 U.S.C. §103(a) as being obvious over U.S. Patent Application Publication No. 2002-0142119 as applied to claim 1 and further in view of U.S. Patent No. 6,388,043 (Langer et al.).

Claims 6-9 have been canceled without prejudice or disclaimer. As such, it is respectfully submitted that this rejection is moot as to claims 6-9. New claims 16-30, which depend directly or indirectly from independent claim 1, are generally directed to the subject matter of canceled claims 6-9.

The Office Action asserts that "Seward et al. disclose[s] the invention substantially as claimed except for the SMP material having an e-module of 0.5 to 50 Mpa (col. 6, lines 66-67), the polymer network comprising caprolactone units (col. 8, lines 11-19), such as cross-linked caprolactonmacromonemers, or a method (col. 12, lines 63-34) of manufacturing the stent from a biodegradable SMP material using extrusion." The Office Action indicates U.S. Patent No. 6,388,043 (which Applicants note is commonly assigned and shares a common inventor as the present application) discloses an "SMP material having an e-module of 0.5 to 50 Mpa for the purpose of strength, the polymer network comprising caprolactone units, such as cross-linked caprolactonmacromonemers, and a method of manufacturing a stent from a biodegradable SMP material using extrusion." Thus, the Office Action concludes that it would have been obvious to modify U.S. Patent Application Publication No. 2002-0142119 with the teachings of U.S. Patent No. 6,388,043 to arrive at the inventioon of claims 6-9 (now claims 16-30).

Applicants reiterate the remarks set forth above regarding U.S. Patent Application Publication No. 2002-0142119 as applied to claim 1 (*i.e.*, that U.S. Patent Application Publication No. 2002-0142119 discloses devices made from a combination of an SMA and an SMP and the present claims are instead directed to a stent that (i) does not include any SMA material or other shape memory

materials other than the non-metallic SMP(s) and (ii) is composed primarily or entirely of at least one material consisting essentially of at least one non-metallic SMP(s)).

Even assuming *arguendo* that U.S. Patent No. 6,388,043 discloses the features asserted by the Office Action, the cited portions of U.S. Patent No. 6,388,043 nonetheless fail to supply the deficiencies of U.S. Patent Application Publication No. 2002-0142119 as discussed above. Moreover, there is no teaching or suggestion, nor does the Office Action provide a rationale in addressing canceled claims 6-9, for modifying the teachings of U.S. Patent No. 6,388,043 to remedy those deficiencies in order to arrive at the stents of claims 16-30.

Therefore it is respectfully submitted that new claims 16-30 cannot be rendered obvious under 35 U.S.C. § 103(a) over over U.S. Patent Application Publication No. 2002-0142119 as applied to claim 1 in view of U.S. Patent No. 6,388,043.

Conclusion

In view of the foregoing, Applicants respectfully requests reconsideration and timely allowance of the pending claims. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact Applicants' undersigned representative to expedite prosecution.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1349. If a fee is required for an extension of time under 37 C.F.R. § 1.136 that is not accounted for in the enclosed transmittal, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Dated: February 21, 2008

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